DOCUMENT RESUME

ED 444 747 PS 028 843

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TITLE Florida Panhandle Healthy Start: A Randomized Trial of Prenatal Home Visitation.
SPONS AGENCY Health Resources and Services Administration (DHHS/PHS), Washington, DC. Maternal and Child Health Bureau.
PUB DATE 2000-00-00
NOTE 23p.; Paper presented at the Head Start National Research Conference (5th, Washington, DC, June 28-July 1, 2000).
PUB TYPE Reports - Research (143) -- Speeches/Meeting Papers (150)
EDRS PRICE MF01/PC01 Plus Postage.
DESCRIPTORS At Risk Persons; *Birth Weight; Comparative Analysis; *Early Intervention; *Home Visits; Infant Mortality; *Infants; Mortality Rate; Mothers; *Premature Infants; Prenatal Care; *Prenatal Influences; Program Evaluation
IDENTIFIERS Florida; *Healthy Start Program

ABSTRACT

Noting prenatal and early childhood home visitation by nurses has had positive effects on birth outcomes in several at-risk populations, this study examined the impact of weekly home visits by systematically trained visitors on birth outcomes of high-risk pregnant women within the context of a Florida Healthy Start project. Participating were eligible pregnant women in 6 Florida counties; 359 were randomly assigned to the treatment group and 169 to the control group. In addition to prenatal care, treatment group women received weekly home visits by nurses or paraprofessional home visitors who promoted healthy lifestyles, coordinated services, and provided education/support through a community network. Control-group women received services available in the community. Results indicated no statistically significant differences in low birth weight, preterm birth, or poor birth outcome between the treatment and control groups. Women with poor previous birth outcomes were 2.9 times more likely to have a poor birth outcome than women without such experience. Women who received services (independent of group status) had lower rates of low birth weight, preterm birth, and poor birth outcomes. Samples were identified as at much greater risk of poor pregnancy outcome than a comparison group of the general pregnant population in Florida during the same time period, contributing to the inability to demonstrate a significant treatment effect on birth outcomes. (Contains 15 references.) (KB)

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Florida Panhandle Healthy Start:

A Randomized Trial of Prenatal Home Visitation

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Contributors

Isabel Stabile M.D., Ph.D. and Mimi Graham Ed.D. recruited provider partners, coordinated the trial, helped obtain continued funding, participated in the analysis and interpretation of data and wrote the paper.

Mimi Graham Ed.D. and Anita Hakes Ph.D. formulated the research hypotheses, obtained initial funding, designed the protocol and initiated the study.

Anne Powell M.S., coordinated the direct service component of the study, and Bill Dahlem Ph.D. coordinated program evaluation.

The late Walt Terry Ph.D. set up the MIS for data collection and analysis, and designed and implemented procedures for quality control of all data collected.

Kwang Lee Chu M.S. and FJ King Ph.D. randomized patients into the study, maintained the databases, analyzed and helped to interpret the data and discussed core findings.

Carolyn Mathers coordinated the recruitment of participants.

Cathy Oakley and Leslie Provis tracked the control group.

The home visitors collected some of the data.

Private and public health care providers referred patients into the trial.

Funding

This study was supported by a grant from the Division of Perinatal Systems and Women's Health of the Bureau of Maternal Child Health, Department of Health and Human Services.

ABSTRACT

INTRODUCTION

Randomized trials of prenatal and early childhood home visitation by nurses have shown positive effects on birth outcomes in young adolescents, smokers[1], and African American women with low social support.[2] Moreover, nurse home visiting has been reported to affect maternal emotional well-being,[3,4] smoking cessation rates, high school graduation, employment and repeat pregnancy rates,[5] emergency room use, immunization, child abuse, neglect and injury rates.[6,7] as well as parenting skills in drug abusing women.[8] Fifteen year follow-up of the original Elmira, NY nurse home visitation study has shown remarkable long term effects in reducing the number of subsequent pregnancies, child abuse and neglect reports, and children's criminal and antisocial behavior.[9] Three year follow-up of a primarily African American cohort of pregnant women who received nurse home visitation services has shown fewer subsequent pregnancies, longer intervals between pregnancies and fewer months of using AFDC and food stamps.[10]

This randomized trial was conducted within the context of a federally funded Healthy Start project. The overall goal of the project was to reduce infant mortality in the project area from 15.8 (1988-90) to no more than 9 deaths per 1,000 by September of 1997, by increasing timely prenatal care, reducing the incidence of late or no prenatal care, decreasing smoking, alcohol and drug use during pregnancy, and improving the nutritional status of pregnant women. In addition, the project aimed to promote child health by increasing the utilization of preventive health services including compliance with the American Academy of Pediatrics' recommended schedule of immunizations for children. Finally, there was an emphasis on increasing parenting skills and enhancing parental responsibility by reducing the incidence of child abuse and neglect and delaying subsequent pregnancies. We hypothesized that babies of high-risk pregnant women

who received weekly home visits by systematically trained home visitors would have different birth outcomes than those who received less intensive home visits available in the target counties. The present report focuses solely on the birth outcome data in this trial population. The accompanying paper[11] examines the differences in birth outcomes in relation to whether the home visitor was a nurse or paraprofessional.

METHODS

The Panhandle Healthy Start project was a randomized controlled study of at-risk pregnant women in six predominantly rural north Florida counties. In addition to prenatal care, women in the treatment group received weekly home visits by either nurse or paraprofessional home visitors. The home visitors promoted healthy lifestyles, coordinated services, and provided education and support to ensure successful pregnancies and healthy babies. The provision of direct services and access to health, educational, social and support services was accomplished through a collaborative community network. Women in the control group received services that were available in the community, including Florida's statewide Healthy Start program.

From April 1995 to September 1997, 528 eligible pregnant women at 25 weeks or less were actively recruited by private and public prenatal care providers in six north Florida counties: Leon, Gadsden, Madison, Jefferson, Taylor and Calhoun. The target population included women who were single, or had less than a high school education, or were Medicaid eligible, or who scored four or more on Florida's Healthy Start Prenatal Risk Screening, or those considered at-risk by their prenatal health care provider. Recruitment was not limited to first time mothers.

Once determined eligible to participate in the program, women were asked to sign IRB-approved informed consent forms. The application forms were faxed or mailed to the study center where randomization occurred within 24 hours of receipt of the completed paperwork. All (n=528) eligible women were enrolled into the project and randomized using a computer-generated table of random numbers at the study center by staff with no direct contact with the service delivery team. Randomization was stratified by county. Women randomized to the treatment group (n=359) were assigned to receive weekly home visits by a either a nurse or a

paraprofessional, while women randomized to the control group (n=169) received nurse case management services available in the community. Forty-four of the 359 women randomized into treatment were not served because either they moved out of the project area (n=9); or they could not be located after at least ten attempts by a combination of telephone, face-to-face contact and mail (n=6); or they miscarried (n=12); or they declined services (n=17).

Once hired, the project coordinator and three supervisors selected 14 home visitors who lived within the project area. All paraprofessionals (n=9) had no more than a high school diploma or GED, although they each had experienced life events that prepared them as home visitors. The nurses had, at a minimum, a RN degree, although two of the five nurses also had a BSN.

Between May 1995 and September 1997, home visitors in the six county project area served a total of 315 high-risk pregnant women. A few of the women were served for a brief period of time and then either elected to be dropped from the program or could not be located. Data analysis includes all randomized women, irrespective of whether they were actually served or the duration of the services they received. The home visitors were trained to consistently follow the protocol to track down participants who were difficult to locate before services were officially discontinued. Each visitor served no more than 15 women at a time and saw each of her clients weekly for at least an hour, focusing on the following:

- ✓ *Education* on the importance of prenatal care, fetal growth, proper weight gain, diet and nutrition, exercise and fitness, emotional health, avoiding sexually transmitted diseases, avoiding the use of alcohol, drugs and tobacco, childbirth preparation, and premature labor warning signs;

- ✓ *Assistance* in enrolling in childbirth preparation classes, paying enrollment fees, and obtaining child care and transportation when they were unavailable;
- ✓ *Referral* to special programs and services, such as smoking cessation programs, mental health counseling, and violence protection services;
- ✓ *Emotional support* and other assistance on a case-by-case basis, including transportation to prenatal visits, crisis intervention, and childbirth coaching.

In parts of the target area, no private or public transportation was available to up to one quarter of the families. In these situations, home visitors took pregnant women to their prenatal and social services appointments utilizing the travel and waiting time to provide additional education and support.

The home visitors utilized the *Partners for a Healthy Baby* Prenatal Home Visiting curriculum, a prescriptive curriculum organized by weekly topics to guide the content of their visits during pregnancy. Careful documentation of the frequency and content of home visits provided a systematic means for reporting client-specific outcome data. The number and types of topics discussed during home visits was used by supervisors for quality improvement and to provide feedback to home visitors in planning what topics still needed to be addressed with each family.

Women randomized to the control group were referred back to the original referral source, usually the County Health Department, to determine if they were eligible for Florida's own state-funded Healthy Start services. Irrespective of whether these services were given, the project's evaluation team attempted monthly phone calls to each control participant to track their use of services available in the community. The infusion of 14 home visitors in the project area had the

immediate effect of dramatically lowering caseloads for the care coordinators serving women in the control group.

The statistical software package, SPSS for Windows version 9.0 was used to perform Chi-square and ANOVA statistical models to test differences between groups in this project, the former for dichotomous or categorical variables and the latter for continuous variables.

Data analysis was driven by a model which assumed that home visitor education and support services (including transportation) were instrumental in affecting uptake of prenatal care, use of tobacco, alcohol and drugs, diet/nutrition and maternal stress, which in turn affected birth outcomes. Other intervening variables included pre-existing risk factors and medical complications of pregnancy, labor and delivery.

RESULTS

A summary of the proportion of participants that met each of the recruitment criteria is shown in Table 1 while gestational age and mother's age at the time of entry into the project are shown in Table 2. For the purpose of the following analyses, all women in each experimental group are combined, irrespective of where they lived in the project area.

Table 1: Percentage of Women Meeting Recruitment Criteria

Criterion	%*
Pregnancy =< 25 weeks[a]	96.9
Single	73.5
< High School Education	45.8
Medicaid Recipient	51.7
Florida Healthy Start Prenatal Risk Screen score >= 4	72.3

Table 2: Pregnancy Trimester and Mother's Age at the Time of Project Entry

Participant Age	First Trimester	Second Trimester	Third Trimester	Total
10-14	6	7	0	13
15-19	91	123	8	222
20-40	124	144	17	285
>40	0	0	0	0
Area Total	221	274	25	520*

*Missing data on 8 participants.

Pre-Intervention Equivalence of Study Groups

In addition to the control group, a comparison group was drawn from the Florida Prenatal Risk Screen electronic database (1995 to 1997). All pregnant women who met at least one of the study's recruitment criteria (single, less than high school diploma, on Medicaid, and risk score greater or equal to 4) were assigned to the comparison group (n = 231,656). Table 3 shows the

background characteristics of the three groups i.e., randomized treatment, randomized control and comparison groups. The control group included significantly more non-white women and those with an illness requiring medical care during pregnancy than the treatment group, while the treatment group had significantly more smokers, and women with a history of previous preterm delivery than the control group. Although there were significantly fewer smokers in the control than in the treatment group, the proportion of smokers in the treatment group was identical to that in the comparison group. Descriptive analysis shows large percentage differences for non-white race, marital status, high Healthy Start score, first pregnancy, problem keeping appointments, physical abuse during pregnancy, change in timing of current pregnancy, previous poor pregnancy outcome, and illness during the index pregnancy between the experimental groups and the comparison group. However statistical testing of these differences was not conducted because the large group size difference would have resulted in unreliable data. These differences support the conclusion that with the exception of smoking, the project sample included women who were at much greater risk of poor pregnancy outcome than a comparison group of women selected during the same time period based on identical risk factors.

Table 3: Background Characteristics of Project Sample & Population Comparison Group

Prenatal Risk Screen Items	T	C	Project Total	FL
Total #	359	169	528	231,656
Age (Average)	20.6	20.7	20.6	23.5
Non-White (%)	73.0	82.7	75.0	45.8
< High School Education (%)	45.9	47.6	46.4	45.8
Single (%)	83.1	82.6	82.9	74.6
First Pregnancy (%)	45.4	49.0	46.6	24.4
Prenatal Risk Score (Average)	4.5	4.5	4.5	3.0
Prenatal Risk Score >= 4 (%)	75.1	77.8	75.9	42.3
1. Problems of keeping appointments (%)	11.9	12.7	12.1	7.5

Prenatal Risk Screen Items	T	C	Project Total	FL
2. Moved more than 3 times in the last 12 months (%)	10.4	7.5	9.5	10.8
3. Feel unsafe where you live (%)	4.3	7.5	5.3	4.4
4. Any member of the household go to bed hungry (%)	4.3	2.2	3.6	3.4
5. Used any form of tobacco in the last 12 months (%)	23.7	14.9	20.9	23.7
6. Used drug or alcohol in the last 12 months (%)	14.1	15.7	14.6	12.4
7. Anyone hit you or tried to hurt you in the last year (%)	8.7	12.0	9.8	6.3
8. Rating of current stress level: High Stress (%)	18.3	16.4	17.7	15.7
9. Change time of pregnancy: No change (%)	33.6	32.8	33.3	40.7
10. Last pregnancy resulted in poor outcome (%)	39.2	30.3	36.5	14.6
11. Illness that requires continuing medical care (%)	*15.8*	*22.6*	18.0	8.2
Previous Obstetrical History: Preterm (%)	***16.0***	***6.8***	5.8	6.2
Previous Obstetrical History: LBW (%)	12.9	8.2	5.1	4.6

- Bold Italic: $p < 0.1$, Underline: $p < 0.05$, Bold: $p < 0.01$

As shown in Table 4, there were no statistically significant differences in low birth weight (LBW) or preterm births, nor poor birth outcome (fetal death or neonatal death or LBW or preterm delivery) between the treatment and control groups. Outcomes for the Florida comparison group could not be obtained because of difficulty in linking the Prenatal Risk Screen and Vital Statistics live birth databases.

Table 4: Pregnancy Outcomes by Treatment Group

Outcome	T (%)	C (%)
Live Birth	324 (90.3)	154 (91.1)
Miscarriage	15 (4.2)	4 (2.4)
Fetal Death	6 (1.7)	3 (1.8)
Unknown[1]	14 (3.9)	8 (4.7)
Total	**359 (100)**	**169 (100)**
Low Birth Weight	39 (12.1)	15 (9.6)
Preterm Birth	41 (12.7)	17 (10.9)
Poor Birth Outcome[2]	59 (18.0)	21 (13.4)

1. 44 women in the treatment group did not receive home visiting services and 47 in the control group did not receive case management services from Florida's Healthy Start program. In a few of them, birth outcomes were not found.
2. Combined variable of fetal death, neonatal death, LBW, VLBW, or preterm delivery.

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The analysis shown in Table 5 examines birth outcome differences between plausible prenatal risk factors (reading between rows) and between experimental groups (reading between columns). Tests of significance were applied within each 2x2 cell for each risk factor. For example, 20.5% of the smoking participants within the treatment group experienced poor birth outcome in the index pregnancy compared with 13.6% of smokers within the control group. Also there was no statistically significant difference in poor birth outcome between smokers and non-smokers in either the treatment or control groups. In other words, although there were significantly more smokers in the treatment group (see Table 3), being a smoker did not apparently influence poor birth outcome rates in either of the experimental groups. Similar findings were noted with respect to being non-white or having a history of preterm birth. i.e., among women in either experimental group, there was no statistically significant difference in poor birth outcome rates between those with and without a history of preterm delivery. These unexpected results are probably due to the small sample size in each cell.

We used a logistic model to further examine the effects of prenatal risk factors (race, smoking and history of LBW or preterm delivery) on birth outcome in the index pregnancy, and showed a significant effect of history of LBW or preterm delivery on current poor birth outcome (odds ratio = 2.9, $p < 0.05$). In other words, women with poor previous birth outcome were 2.9 times more likely to have a repeat poor birth outcome than those whose previous pregnancies did not result in LBW or preterm delivery, as expected from the obstetrical literature.

Women who self-reported low stress, those who were married or 19 or younger, those with less than a high school education, and those with a Healthy Start prenatal screen score of 4

or more, had statistically significantly lower rates of poor birth outcome in the control group than the treatment group.

Comparing the proportion of participants with poor birth outcome within each experimental group and between contrasting factors, (for example, treatment group across rows of risk factors), there are statistical differences in previous LBW history, stress, mother's age, and first pregnancy in the treatment but not in the control group. As expected more women with a history of preterm delivery had poor birth outcome in both experimental groups, although the finding was not significant, probably due to the small sample size in each cell. However, for all remaining statistically significant differences in poor birth outcome rates, the direction of the difference was opposite in the treatment and control groups. For example, the control group had poor birth outcome rates that increased as stress levels or maternal age increased, and decreased as the Healthy Start risk score increased. Conversely, the treatment group had lower poor birth outcome rates when stress levels or age increased, and a higher rate as the risk score increased.

Table 5: Percentage Poor Birth Outcome by Prenatal Risk Factors and Experimental Group

	T	C
Smoker	20.5	13.6
Nonsmoker	16.7	13.3
With Preterm History	32.0	25.0
Without Preterm History	18.6	9.5
With LBW History	42.9	33.3
Without LBW History	17.3	8.2
Low Stress	27.8	10.2
Medium Stress	15.8	15.5
High Stress	6.5	20.0
White	16.9	12.5
Nonwhite	18.1	13.5
Age =< 19	23.4	10.5

	T	C
Age >19	13.5	16.0
High School Graduate	14.7	17.6
Not High School Graduate	**22.3**	**8.3**
Married	16.7	0.0
Single	17.2	16.5
Healthy Start Prenatal Screen Score 3 or Less	12.8	22.6
Healthy Start Prenatal Screen Score 4 or more	19.0	11.0
First Pregnancy	12.4	16.9
Not First Pregnancy	21.3	9.7

Underline: $p < 0.05$, Bold: $p < 0.01$, 1-sided exact test

In order to examine the effect of home visiting services, birth outcomes for trial women were recombined into two groups: the "served" group combines the women in the treatment group with those in the control group that received any Healthy Start home visiting services. The "not served" group combines the 44 women randomized to the treatment group who did not receive services with the 47 women in the control group who did not receive the services offered in their community. Table 6 shows that the women who received services (whether in the treatment or control groups) had lower LBW, perterm birth, and poor birth outcome rates than those who did not receive any home visiting services.

Table 6: Birth Outcome Rates by Group

Birth Outcome	Served (%)	Not Served (%)
Low Birth Weight	10.7	15.0
Preterm Birth	11.7	14.8
Poor Outcome[1]	15.9	21.0

1. Combined variable: fetal death, neonatal death, LBW, VLBW, or preterm delivery.

Table 7 shows the percentage of women in the served and not served groups with a poor birth outcome for each of the prenatal risk factors. Overall, with the exception of smokers, those

under stress, non high school graduates and those under 19 years of age, birth outcome was better in the served group than in the not served group with similar risk factors. Women with a history of LBW delivery and those who were 19 or younger were significantly more likely to experience poor birth outcomes than their peers without these risk factors in the served but not the not served groups.

Table 7: Percentage Poor Birth Outcome by Prenatal Risk Factors and Service Groups

	Served (%)	Not Served (%)
Smoker	20.5	8.3
Nonsmoker	14.5	22.4
With Preterm History	26.9	66.7
Without Preterm History	15.8	14.3
With LBW History	**37.5**	66.7
Without LBW History	**14.5**	14.3
Low Stress	22.2	7.7
Medium Stress	13.5	36.8
High Stress	10.7	10.0
White	16.3	13.3
Nonwhite	15.8	21.7
Age =< 19	19.5	14.8
Age >19	12.9	23.5
High School Graduate	14.4	26.9
Not High School Graduate	17.9	16.7
Married	9.7	22.2
Single	16.1	23.3
Healthy Start Prenatal Screen < 3	14.1	23.5
Healthy Start Prenatal Screen >= 4	15.9	20.0
First Pregnancy	13.1	20.0
Not First Pregnancy	17.6	19.2

• Underline: $p < 0.05$, Bold: $p < 0.01$

For seven of the ten risk factors examined in Table 7 the pattern of poor birth outcome rate is such that the direction of difference is opposite between the served and not served groups. Moreover, the direction of the data is similar to that in Table 5 (randomized treatment versus

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control), implying that home visiting services whether provided through Panhandle Healthy Start or the community, influenced birth outcomes in the same manner.

COMMENT

Case management through home visiting was chosen as the primary service delivery strategy of the Florida Panhandle Healthy Start project in response to (a) dramatic shortage of health care providers in the rural Panhandle; (b) evidence that low-income, minority women are particularly responsive to home visiting programs,[12] evidence supporting the cost benefits of home visiting;[13] (d) research that the more successful programs began during pregnancy, followed-up families at least through the second year of life, and focused their work on families at greatest need [14] by providing care coordination and enhanced services in a location that best meets the individual concerns, priorities and resources of the family, their home. The original prenatal home visitation trial in Elmira, NY by Olds and colleagues was conducted with primarily white women who had no previous live births and who lived in a semi-rural area. By contrast, the randomized Memphis study by the Olds group was conducted with an African-American sample of primarily low income, unmarried women living in a major urban area.[15] Unlike these two trials, we included women who had previous live births (almost half our sample), or had chronic illness in pregnancy (almost 20% of our sample). Moreover, the sample group in this study included women who were at much greater risk of poor pregnancy outcome than a comparison group of the general pregnant population in Florida during the same time period. This may perhaps explain why, unlike in these two nurse home visitation studies, we were unable to demonstrate a significant treatment effect on birth outcomes.

Unlike the Olds trials that are both considered efficacy trials where the intervention brings about its intended effect under ideal conditions, our trial was designed as an effectiveness study to determine whether home visiting can affect birth outcomes when deployed in the field under real world conditions. For example, in our study, the home visitors faced barriers in consistently accomplishing weekly home visits: they had high risk participants who were widely dispersed in rural communities, who moved often, and many of whom did not have access to telephones. Moreover, some participants did not fully understand that the program consisted of weekly visits. Special arrangements were made to reduce the frequency of visits to accommodate the families' needs. These factors may in part explain the relatively low mean number of visits in the treatment group (12.9, SD 7.4). Lastly, data on all women randomized into the study were analyzed, although we could have been justified in excluding women who were randomized to treatment but did not actually receive any services. Also, had we preceded the trial with a pilot period, we might have learned better ways to recruit, retain and serve this cohort of women.

Perhaps because randomization was not stratified by risk factors, the control group had significantly more non-whites and those with an illness requiring continuing medical care, while the treatment group included significantly more tobacco users and more than twice as many women with history of a previous preterm birth than the control group. Not only are these factors associated with poor birth outcome in the literature, but logistic analysis of our own data showed a significant effect of previous poor birth outcome on poor birth outcome in the index pregnancy. Considering that twice as many women in the treatment group had a previous preterm delivery, it is surprising that the LBW or preterm delivery rate was not significantly different between the treatment and the control groups (Table 4).

For several of the risk factors examined in Tables 5 and 7, the pattern of poor birth outcome rates is opposite in the treatment than in the control group as well as in the served and the not served groups. This implies that the home visitation services provided to women in the treatment group preferentially influenced birth outcomes in older women, those who were at higher stress, or those with a previous LBW birth.

One of the plausible explanations for these unexpected outcome distributions is the definition of the experimental group itself. Some women (n=44) randomized to the treatment group did not receive any home visiting services while 47 women in the control group received services from other public health agencies. In addition, the project reduced the workload for nurse case managers providing services to women in the control group. In Tables 4 and 5, these women who did not receive any home visiting services are included in their respective experimental group (i.e., analysis by intention to treat). Although we hypothesized that the prenatal home visitation intervention would result in improved birth outcomes, and this was not the case, analysis of served versus not served women (Table 6) shows that prenatal home visitation/case management services was associated with lower LBW, perterm birth, and poor birth outcome rates among those who actually received home visiting services.

These findings must be viewed with caution. First, the sample group is relatively small and unbalanced, which limits our ability to test the significance between group means. Second, the sample group included women who were at much greater risk of poor pregnancy outcome than a comparison group of the general pregnant population in Florida during the same time period. Third, before the provision of services, the treatment group differed from the control group women with respect to certain risk factors, such as race, use of tobacco and history of

previous preterm delivery. We attempted to adjust statistically for these pre-intervention differences, but it is possible that there are other associated conditions that biased the sample in unknown ways. Moreover, because the proportion of women with poor birth outcome was less than 10 percent of the total sample, the ability of statistical tests to examine group differences was limited. In this case, it may be more useful to examine whether there are statistically significant differences in positive birth outcomes between the experimental groups, and the nature of their relationship to various risk factors.

Another possible explanation for the lack of treatment effect is that the target area experienced a "lateral effect". Although we were unable to document actual caseloads for the nurses who served women in the control group, it is quite likely that the infusion of considerable resources in the form of federal Healthy Start funded home visitors indirectly improved the ability of the Florida Healthy Start care coordinators (who served women in the control group) with their work.

In conclusion, intensive prenatal home visitation in this high-risk rural population did not appear to improve birth outcomes for those receiving services in the treatment group. High risk women who received home visitation services whether in the treatment or in the control groups experienced significantly better birth outcomes than those who received no services at all. Given limited resources, the finding that women experiencing stress, and those having their first pregnancy appeared to benefit the most, would suggest that targeting home visiting services to these high risk groups would be most cost-effective.

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